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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT

Desk Assessment of Finished Product Manufacturer

Part 1	**General information**
Company information	
Name of Manufacturer	Mylan Laboratories Limited
Corporate address of manufacturer	Plot 564/ A/ 22 Road number 92 Jubilee Hills Hyderabad 500 096 Telangana India
Inspected site	
Name & address of manufacturing site	Mylan Laboratories Limited Plot No H12 & 13, MIDC, Waluj Industrial area Aurangabad, 431 136 Maharashtra, India Phone +91-240-666-8888 DUNS. 863 996 098
Production Block/Unit	N/A
Manufacturing license number	The GMP certificate as well as the manufacturing license were issued by the Food & Drugs Administration, Maharashtra. License number 28-AD/064 and 25-AD/089.
Desk assessment details	
Date of review completion	21 December 2022
Products covered by this desk assessment	HA414, Prequalified, Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 300mg/300mg HA417 Prequalified Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 200mg/300mg HA572 Prequalified Lamivudine/Zidovudine Tablet, Dispersible 30mg/60mg HA721Abridged Prequalified Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg HA426 Prequalified Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg TB386 Abridged Prequalified Pretomanid Tablet 200mg HA433 Prequalified Lamivudine/Nevirapine/Zidovudine Tablet,

	Dispersible 30mg/50mg/60mg IN011 Prequalified Oseltamivir (phosphate) Capsules, hard 75mg HA444 Prequalified Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg TB308 Prequalified Isoniazid Tablet 100mg HA466 Prequalified Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/300mg/300mg HA683 Prequalified Darunavir (ethanolate) Tablet, Film-coated 800mg HA685 Prequalified Darunavir (ethanolate) Tablet, Film-coated 600mg TB304 Prequalified Cycloserine Capsules, hard 250mg TB285 Prequalified Isoniazid Tablet 300mg HA392 Prequalified Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg HA403 Prequalified Efavirenz Tablet, Film-coated 600mg HA410Prequalified Tenofovir disoproxil fumarate Tablet, Film-coated 300mg
List of documents submitted	a) A list of all regulatory inspections performed in the last 5 years and their outcomes; b) Current full inspection report(s), including deficiency letters, for inspections performed by a competent stringent regulatory authority in the past three years with a certified translated copy where this is not in English; c) Proof of CAPA implementation and final decision by the competent stringent regulatory authority related to observations or deficiencies noted in the latest inspection report or to any warning letter or equivalent regulatory action (production-line specific); d) A copy of the manufacturing authorization and GMP certificate granted by the local national authority together with a certified translation, where this is not in English; e) A site master file whose approval date was not more than one year ago, and any forecast modifications, together with legible color printouts of water treatment and air-handling systems, including pipeline and instrumentation drawings in A3 or A2 format; f) The list of all the products and dosage forms manufactured on-site. The list should include proprietary names and International Nonproprietary Names (INN), including all types of chemicals and products (e.g., pesticides, herbal medicines, chemicals or veterinary products, etc.); g) The most recent product quality review(s) (PQR)(s) of the concerned product(s); PQR(s) or equivalent documentation covering all required subsections and trend results, including statistical evaluation; h) The completed batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s); i) The list of any recalls in the past three years related to any product manufactured on site with quality defects; j) A confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product(s) has been

	performed and all matters dealt with; k) Master batch manufacturing and packaging record(s) of the WHO product(s) of interest; l) Copy of any warning letter, or equivalent regulatory action, issued by any authority to which the site provides or has applied to provide the product; m)Description of any recent or foreseen out-of-stock situations; n) A list of notifications of upcoming inspections by competent national regulatory authorities in the next 6 months; o) Table to specify which parts of the manufacturing process for the concerned product(s) were covered by the inspection of the competent SRA authorities performed in the last 3 years	
Any documents missing?	N/A	
Part 2	**Summary of SRA/NRA inspection evidence considered (from most recent to last) and comments**	
USA FDA	Dates of inspection:	20, 21 and 24 to 28 February 2020
	Type of inspection:	GMP
	Block/Unit:	Complete facility
	Type of products/Dosage forms covered:	Tablets and capsules
	Physical areas inspected:	The inspection covered quality systems, materials, facilities and equipment, production, laboratory, packaging and labeling. No FDA 483 was issued, only one observation was discussed verbally.
	Any sections of GMP not covered?	N/A
	Final conclusion of the inspection report:	Compliant with GMP
	Comments/observations on the scope and comprehensiveness of the inspection report and on the appropriateness of the CAPAs in lieu of an onsite inspection by WHO:	Acceptable.
Health Products Regulatory Authority, (HPRA) Ireland	Dates of inspection:	25 to 29 November 2019
	Type of inspection:	General GMP inspection
	Block/Unit:	N/A
	Type of products/Dosage forms covered:	Non-sterile oral sold dosage forms (tablets and capsules)
	Physical areas inspected:	Pharmaceutical Quality System Corrective and Preventative Actions (CAPAs) Product Quality Reviews (PQRs)

		Deviation Management Change Management Batch Certification Personnel Gowning & Hygiene Training Premises and Equipment Calibration Maintenance Equipment Qualification Heating, Ventilation and Air Conditioning (HVAC) Systems Purified Water System Computerized Systems Documentation Production Supplier Management Excipient Risk Assessment Control of Contamination & Cross Contamination Environmental Monitoring (EM) Cleaning of Equipment & Facilities Cleaning Validation Manufacturing Processes Packaging Processes Process Validation Warehouse and Materials Management System Quality Control Physical/ Chemical Laboratory Laboratory Investigations Microbiological Laboratory In-Process Control Laboratory Management of Stability Samples Quality Control Analytical Method Validation & Transfer Outsourced Activities Technical Agreements Audits Complaints Quality Defects and Product Recalls Customer Complaints Product Recalls Self-inspection
	Final conclusion of the inspection report:	Compliant with GMP

	Comments/observations on the scope and comprehensiveness of the inspection report and on the appropriateness of the CAPAs in lieu of an onsite inspection by WHO:	Acceptable
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	The last inspection done by WHO, Geneva, was in 2016.	
Summary of manufacturing activities	Non sterile oral solid dosage forms. (Tablets and capsules)	
General information about the company and manufacturing site	Production, packaging, quality control of tablets and capsules (non sterile oral solid dosage forms)	
Focus of the last WHO inspection	General GMP compliance, OSD forms	
Areas inspected	Production and control of OSD forms	
Out of scope and restrictions (last WHO inspection)	*N/A*	
WHO products covered by the last WHO inspection	IN009 Oseltamivir (phosphate) 30mg Capsules, hard IN0I0 Oseltamivir (phosphate) 45mg Capsules, hard IN011 Oseltamivir (phosphate) 75mg Capsules, hard TB285 Isoniazid (under assessment) 300mg Tablet TB304 Cycloserine Capsules (under assessment) 250mg Capsules, hard HA396 Nevirapine 200mg Tablet HA403 Efavirenz 600mg Tablet, Film coated HA414 Lamivudine/Tenofovir disoproxil (fumarate) 300mg/300mg Tablet, Film coated HA417 Emtricitabine/Tenofovir disoproxil (fumarate) 200mg/300mg Tablet, Film coated HA426 Lamivudine/Nevirapine /Zidovudine l50mg/200mg/300 mg Tablet, Film coated	

	HA444 Efavirenz/Emtricitabine /Tenofovir disoproxil (fumarate) 600mg/200mg/300mg Tablet, Film coated HA466 Efavirenz/Lamivudine/Tenofovir disoproxil (fumarate) 600mg/300mg/300 mg Tablet, Film coated HA477 Atazanavir (sulfate) 300mg Capsules, hard HA478 Atazanavir (sulfate) 150mg Capsules, hard HA501 Lamivudine/Tenofovir disoproxil (fumarate) + Nevirapine 300mg/300mg +200mg Tablet HA572 Lamivudine/Zidovudine 30mg/60mg Tablet, Dispersible HA612 Fluconazole 50mg Tablet, Dispersible HA613 Fluconazole 200mg Tablet, Dispersible HA614 Clarithromycin 500mg Tablet, Film coated HA625 Acyclovir (under assessment) 200mg Tablet HA626 Acyclovir (under assessment) 400mg Tablet
Additional products to be covered by this desk assessment:	HA721 Abridged Prequalified Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg TB386 Abridged Prequalified Pretomanid Tablet 200mg HA433 Prequalified Lamivudine/Nevirapine/Zidovudine Tablet, Dispersible 30mg/50mg/60mg TB308 Prequalified Isoniazid Tablet 100mg HA683 Prequalified Darunavir (ethanolate) Tablet, Film-coated 800mg HA685 Prequalified Darunavir (ethanolate) Tablet, Film-coated 600mg TB304 Prequalified Cycloserine Capsules, hard 250mg HA392 Prequalified Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg HA403 Prequalified Efavirenz Tablet, Film-coated 600mg HA410 Prequalified Tenofovir disoproxil fumarate Tablet, Film-coated 300mg
Abbreviations	**Meaning**
AHU	Air handling unit
API	Active pharmaceutical ingredient
BMR	Batch manufacturing record
BPR	Batch production record
CAPA	Corrective and preventive action
CC	Change control
FPP	Finished pharmaceutical product
GMP	Good manufacturing practices
NC	Non-conformity
NRA	National regulatory agency
PQR	Product quality review
PQS	Pharmaceutical quality system
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system

QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SMF	Site master file
SOP	Standard operating procedure

Part 4	**Summary of the assessment of supporting documentation**

a) List of all regulatory inspections performed in the last 5 years and their outcomes:

Belarus Health Authority,	2022
CDSCO, India,	2021
ZAZIBONA,	2021
USA FDA,	2020
Health Products Regulatory Authority, Ireland,	2019
Ministry of Health, Russia,	2019
USA FDA,	2019
Pharmaceuticals and Medical Device Agency, Japan,	2019
CDSCO,	2018
TFDA, Tanzania,	2017
Health Products Regulatory Authority, Ireland,	2017
NDA, Uganda,	2017

b) Manufacturing authorization granted by national authorities:

The GMP certificate as well as the manufacturing license were issued by the Food & Drugs Administration, Maharashtra.

c) Site master file:

A 261 page SMF was submitted, dated October 2022, and was found acceptable

d) List of all the products and dosage forms manufactured on-site:

Submitted and reviewed.

e) Most recent product quality review(s) (PQR)(s) of the concerned WHO product(s):

Various PQRs (for 18 products) were submitted for review.

Tenofovir/Lamivudine (300mg/300mg): HA 414: 18 batches were produced during the period of review. The company had no rejected batches. OOT results were observed in stability data, and process capability index was calculated. There were no recalls, no reworks and no repackaging activities. Post marketing commitments, changes and incidents were reviewed. In general, all aspects of the PQR as required in GMP were included in the PQR. No significant observations were made.

Emtracitabine / Tenofovir 200/300mg: HA 417: 20 batches were produced during the period of review. The company had no rejected batches. One OOS result and some OOT results were observed and investigated. Process capability index was calculated. There were no product complaints, no recalls, no reworks and no repackaging activities. Post marketing commitments, changes and incidents were reviewed. In general, all aspects of the PQR as required in GMP were included in the PQR. No significant observations were made.

Lamivudine/Zidovudine 30mg/60mg. HA 572. No batches of the WHO Prequalified product were manufactured.

Emtracitabine/Lamivudine/Tenofivir 400mg/300mg/300mg. WHO SFG code. No batches were manufactured.

Pretomanid 200mg. TB386. No document or data to date for manufacturing.

f) Batch manufacturing and packaging record(s), including the analytical part, for the most recently released batch of relevant product(s):

Various BMRs were submitted for review. No significant deviations from GMP were observed.

g) Master batch manufacturing and packaging record(s) of the product(s) of interest:

Master batch manufacturing and packaging documentation were submitted for various products. No significant observation was made

h) If any of the products are sterile, the completed batch records for the most recent media fill validation that is relevant to the product(s) of interest and report on its outcome:

N/A

i) Recalls in the past three years related to products with quality defects:

There had been no recalls in the past three years

j) Confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product(s) has been performed and all matters dealt with:

A confirmation was submitted, that self-inspections were done.

k) Copy of any warning letter, or equivalent regulatory action, issued by any authority to which the site provides or has applied to provide the product:

No warning letter had been issued to this site.

k) Out-of-stock situations:

No out-of-stock situation had been experienced or was anticipated.

l) Additional documents submitted:

N/A

Part 5	Conclusion – Desk assessment outcome

Based on the previous WHO inspections and on the GMP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***Mylan Laboratories Limited*** located at ***Plot No H12 & 13, MIDC, Waluj Industrial area, Aurangabad, 431 136, India*** is considered to be operating at an acceptable level of compliance with WHO GMP guidelines.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 6	List of guidelines referenced in this inspection report

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO TRS No. 957, Annex 2***
untitled (digicollections.net)

3. WHO guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9. ***Short name: WHO TRS 1010, Annex 9***
https://digicollections.net/medicinedocs/documents/s23457en/s23457en.pdf

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3.
Short name: WHO TRS No. 1033, Annex 3
9789240020900-eng.pdf (who.int)

5. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
Short name: WHO TRS No. 929, Annex 4
https://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf

6. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8**
https://digicollections.net/medicinedocs/documents/s23455en/s23455en.pdf

7. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4.
Short name: WHO TRS No. 937, Annex 4
https://digicollections.net/medicinedocs/documents/s20108en/s20108en.pdf

8. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
Short name: WHO TRS No. 961, 957), Annex 1
https://digicollections.net/medicinedocs/documents/s18681en/s18681en.pdf

9. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
Short name: WHO TRS No. 957, Annex 3
https://digicollections.net/medicinedocs/documents/s22358en/s22358en.pdf

10. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.
Short name: WHO TRS No. 961, Annex 6
https://digicollections.net/medicinedocs/documents/s19959en/s19959en.pdf

11. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
Short name: WHO TRS No. 961, Annex 7
https://digicollections.net/medicinedocs/documents/s18677en/s18677en.pdf

12. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. ***Short name: WHO TRS No. 961, Annex* 9**
https://digicollections.net/medicinedocs/documents/s18683en/s18683en.pdf

13. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-first Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
https://digicollections.net/medicinedocs/#d/s21438en

14. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
Short name: WHO TRS No. 961, Annex 2
https://digicollections.net/medicinedocs/documents/s18682en/s18682en.pdf

15. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2.
Short name: WHO TRS No. 981, Annex 2
https://digicollections.net/medicinedocs/#d/s20177en/

16. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3.
Short name: WHO TRS No. 981, Annex 3
https://digicollections.net/medicinedocs/#d/s20175en/

17. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14.
Short name: WHO TRS No. 961, Annex 14
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

18. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3. ***Short name: WHO TRS No. 1019, Annex 3***
https://digicollections.net/medicinedocs/documents/s23697en/s23697en.pdf

19. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. ***Short name: WHO TRS No. 992, Annex 4***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

20. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. ***Short name: WHO TRS No. 992, Annex 5***
Essential Medicines and Health Products Information Portal (digicollections.net)

21. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4. ***Short name: WHO TRS No. 1033, Annex 4***
9789240020900-eng.pdf (who.int)

22. WHO general guidance on variations to multisource pharmaceutical products. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report* Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

23. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10.
Short name: WHO TRS No. 1010, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

24. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditionning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2. **Short name: WHO TRS No. 1019, Annex 2**
https://digicollections.net/medicinedocs/documents/s23699en/s23699en.pdf

25. Points to consider when including Health-Based Exposure Limits in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2. **Short name: WHO TRS No. 1033, Annex 2**
9789240020900-eng.pdf (who.int)

26. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6. **Short name: WHO TRS No. 1025, Annex 6**
9789240001824-eng.pdf (who.int)

27. Production of water for injection by means other than distillation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 3. ***Short name: WHO TRS No. 1025, Annex 3***
https://www.who.int/publications-detail/978-92-4-000182-4

28. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4. ***Short name: WHO TRS No. 1025, Annex 4***
https://www.who.int/publications-detail/978-92-4-000182-4